

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.114, are respectfully requested.

By the foregoing amendment, claim 24 has been amended to recite that the claimed naked DNA is administered "directly to the muscle cells of a patient in need of such treatment." Support for this amendment can be found on at least page 11, lines 3 through 24 of the specification. Claims 25 and 33 have hereby been canceled without prejudice or disclaimer to the subject matter recited therein. Further, claims 46-51 have been added by the present amendment. Support for new claims 46-51 can be found throughout the originally filed application. In particular, support for claim 46 can found on at least page 8, line 18 through page 9, line 2 of the specification; support for claim 47 can be found on at least page 9, lines 2 through 16 of the specification; support for claim 48 can be found on at least page 9, lines 16 through 22 of the specification; support for claim 49 can be found on at least page 11, line 36 through page 12, line 8 of the specification; and support for claims 50 and 51 can be found on page 13, line 24 through page 14, line 2 of the specification. Thus, no new matter has been added by the present amendment.

Despite Applicant's arguments in the Amendment and Reply filed on August 20, 2003, the Examiner maintained the rejection of claims 24, 25, 33 and 43 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not provide sufficient enablement for a method of treating any demyelinating disease or wherein the nucleic acid

is administered by any route. *See* Advisory Action (Continuation Sheet). Applicant respectfully traverses this rejection.

The Examiner has affirmatively stated that the specification is enabling for a method of treating multiple sclerosis and wherein the nucleic acid is directly administered to muscle cells. *See* February 20, 2003 Official Action at page 2, ¶ 7.

As mentioned above, claims 25 and 33 have been canceled without prejudice or disclaimer to the subject matter recited therein. It is noted that independent claim 24, and dependent claims 43 and 46-51, are drawn to a method of treating multiple sclerosis. Moreover, to expedite prosecution in the present application and not to acquiesce to the Examiner's rejection, independent claim 24 has been amended to recite that the claimed naked DNA is administered "directly to the muscle cells of a patient in need of such treatment."

In view of the above, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

In the Advisory Action, the Examiner also maintained the rejection of claim 25 under 35 U.S.C. § 102(b) as allegedly being anticipated by Croxford et al. (THE JOURNAL OF IMMUNOLOGY, 160:5181-5187 (1998)), by Triantaphyllopous et al. (ARTHRITIS & RHEUMATISM, 42:90-99 (1999)), and by Triantaphyllopous et al. (GENE THERAPY, 5:253-263 (1998)). These rejections are respectfully traversed.

Claim 25 has been canceled. Hence, the Examiner's rejections under 35 U.S.C. § 102(b) are rendered moot. Accordingly, the Examiner is respectfully requested to withdraw such rejections.

Finally, in the Advisory Action, the Examiner maintained the rejection of claims 24, 25, 33 and 43 under 35 U.S.C. § 103(a) as purportedly obvious over Triantaphyllopoulos (1998) in view of Youssef et al. (THE JOURNAL OF IMMUNOLOGY, 161:3879 (1998)) and Felgner et al. (U.S. Patent No. 5,580,859). This rejection is also traversed.

The rejection as it applies to claims 25 and 33 is rendered moot since such claims have been canceled without prejudice or disclaimer to the subject matter recited therein.

As to independent claim 24, and dependent claims 43 and 46-51, Applicant respectfully submits that the combination of references fails to teach or suggest the claimed invention. Moreover, absent the use of impermissible hindsight reconstruction, one of ordinary skill in the art would not have been motivated to treat multiple sclerosis comprising administering directly to the muscle cells of a patient in need of such treatment an effective amount of naked DNA comprising a nucleic acid encoding beta-interferon which comprises a beta-interferon secretory signal, wherein said naked DNA is suitable for administration by injection.

In view of the above, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

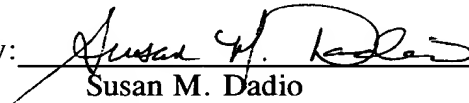
In the event that there are any questions concerning this Amendment and Reply or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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By: \_\_\_\_\_



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